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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,429	03/24/2004	Wing Cheung	38081-00037	4423

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,429	CHEUNG ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *204-244* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *204-244* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Specification

The amendment filed 3/24/04 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: incorporation by reference of 09/569,612 is new matter. The '612 application was not incorporated by reference in the originally filed specification. As the preliminary amendment of 3/24/04 is NOT recited in the execute declaration filed the same date, the preliminary amendment is not considered part of the originally filed disclosure. The language of the amendment is ambiguous, however, and may be interpreted to mean that only the Provisional application is to be incorporated by reference. As the Provisional application was incorporated by reference in the originally filed specification, this would not be new matter. This objection may be overcome by amending the specification to clearly state that only the Provisional application is incorporated by reference.

Applicant is required to cancel the new matter in the reply to this Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 205 and 223-236 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17-30, respectively, of prior U.S. Patent No. 6,747,002. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims of '002 are directed to a method of administering EPO to a patient, wherein administration is a narrower embodiment of the instantly claimed method of "providing" EPO to a patient, thus the claims of '002 anticipate the instant claims.

Claims 204, 208-222 rejected under the judicially created doctrine of double patenting over claims 1-16, respectively, of U. S. Patent No. 6,747,002. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '002 are directed to a method of administering EPO to a patient, which is a narrower embodiment of the instantly claimed method of "providing" EPO to a "consumer", thus the claims of '002 anticipate the instant claims.

Claims 206-207 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,747,002 in view of CHEUNG et al. (Clin. Pharm. Therapeut. (10/1998) vol. 64, no. 4, pages 412-423).

Claims 206 and 207 limit the consumer in the method of claim 204 to be a physician or a healthcare professional.

Claim 1 of '206 recites a method similar to that of claim 204, wherein the dosage is provided to a patient. The claims of '206 do not recite providing an EPO dosage regimen to a physician or healthcare professional.

CHEUNG teaches a method of providing EPO to a patient in a randomized, placebo-controlled study (p. 414). CHEUNG teaches that his studies were performed with the approval of an ethics committee and that dosages were administered at a study site, thus his dosing

regimens must necessarily have been provided to the committee members (healthcare professionals) and to physicians.

It would have been obvious to one of skill in the art at the time of invention to have provided the dosage regimen of '002 to physicians and healthcare professionals, as taught by CHEUNG, in addition to the patient in claim1 of '002, where the motivation would have been to have provided medication in an ethical and clinically-approved manner, as taught by CHEUNG.

In response to applicant's argument that the instant claims are those of Group X set forth in the restriction requirement of parent case 09/569,612, which matured into patent '002, applicant is reminded that NO claims reciting the specific dosage limitations now recited in both the patented and amended instant claims were subject to restriction in the parent application. Where claims were not presented in a parent application at the time of restriction, the later-filed claims are not shielded from double-patenting under 35 USC 121. See Geneva Pharmaceuticals Inc. V. GlaxoSmithKlein PLC, 68 USPQ2d 1865 (CAFC 2003).

Claim Rejections - 35 USC § 112, 1st para

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 242-243 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A purified hyperglycosylated EPO is new. The originally filed claims did not recite any limitation with regard to glycosylation of EPO. New claims 242-243 were entered in a preliminary amendment filed 3/24/04 which is NOT referenced in the executed declaration filed on the same date, therefore the preliminary amendment is not considered part of the originally filed disclosure. The originally filed specification discloses that EPO with "altered" glycosylation may be used in the inventive methods, on page 24, and refers to WO9911781. It is noted that WO9911781 is not incorporated by reference and teaches several forms of EPO with altered glycosylation levels, including EPO which is not glycosylated (p.8). A teaching for EPO with altered glycosylation levels is therefore not a specific disclosure for use of hyperglycosylated EPO in the claimed method. The original specification also discloses darbepoietin, which is a single example of a hyperglycosylated EPO. It is noted that a single example (species) is not representative nor descriptive of the entire group (genus) encompassed by new claims 242-243, therefore the disclosure for darbepoietin does not provide support for the breadth encompassed by the new claims. Applicant does not point to support, in any amendment or response, for the newly recited limitations of claims 242-243.

As neither the originally filed specification or claims disclosed or recited a hyperglycosylated EPO, claims 242-243 recite new matter.

Claim Rejections - 35 USC § 112, 2nd para

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 242-243 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 242 and 243 recite a "hyperglycosylated" EPO. The term "hyperglycosylated" is not defined by the specification and may have any of several meanings, including (relative to a wild type EPO): increased number of glycosylation sites (whether or not those sites are actually glycosylated), increased number of glycosylated sites (e.g. through differential processing but without a change in the number of sites), or an increased number of charges per site (e.g. with more highly branched sugars). As it is unclear what limitation of EPO is intended by the term "hyperglycosylated", the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims are rejected under 35 U.S.C. 102(b) as being anticipated by GOLDBERG (Amer. J. Surgery (12/1995) vol. 170, no. 6A (suppl), pp. 37S-43S).

GOLDBERG teaches a method of subcutaneously administering 600 U/kg epoetin alfa to patients on days 1 and 10, which dosage regimen increases reticulocytes (red blood cell production) for about 24 days (p. 42S and Figure 4), thereby anticipating claims 204-205, 208-212, 216, 218-222, 234 and 237.

Claims 204-213, 216-218, 220, 222-224, 226-228, 230, 234, and 237 are rejected under 35 U.S.C. 102(s) as being anticipated by CHEUNG et al. (Clin. Pharm. Therapeut. (10/1998) vol. 64, no. 4, pages 412-423).

CHEUNG teaches a method of providing EPO to a patient wherein the dosing regimen is 600 IU/kg once per week and maintains a serum EPO level above a predose level for 5-6 days (p. 417 and Fig.2), thus anticipating claims 204-205, 211-212, 216, 220, and 237. CHEUNG teaches that his EPO is epoeitin alfa and that dosages of 900 IU/kg (p. 418 and Table III), or 40,000 IU/ml, at no more than 2 ml per dose (p. 414 were administered, thus anticipating claims 213, 217-218, and 221-222. CHEUNG teaches that his dosing regimen can maintain increased blood cell production for 22 days (p. 418 and Figure 7), thus anticipating claims 208-210. CHEUNG administers his EPO both intravenously and subcutaneously (pp. 413-414), thus anticipating claim 234. CHEUNG further teaches that his studies were performed with the approval of an ethics committee and that dosages were administered at a study site, thus his dosing regimens must have been provided to the committee members (healthcare professionals) and to physicians, therefore claims 206-207 are anticipated. CHEUNG teaches that his dosage regimen is used to treat anemia, specifically anemia associated with chemotherapy, and anemia associated with zidovudine treatment of AIDS patients (p. 420), thus anticipating claims 226-228 and 230.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

> matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 214-215 and 229 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (Clin. Pharm. Therapeut. (10/1998) vol. 64, no. 4, pages 412-423) as applied to claims 204-213, 216-218, 220, 222-224, 226-228, 230, 234, and 237, in view of SHINSHI et al. (IDS ref: JP 02096353).

CHEUNG teaches a method of administering/providing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days, using dosages of dosages of 900 IU/kg (p. 418 and Table III), or 40,000 IU/ml, and wherein anemia related to chemotherapy may be treated, as set forth above. CHEUNG does not teach dosing once every two weeks nor anemia related to cisplatin chemotherapy.

SHINSHI teaches a method of dosing with EPO to achieve a desired PK/PD response, wherein EPO is administered at least once every two weeks and may be administered to patients suffering from cisplatin-related chemotherapy (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to have chosen a dosing regimen for any chemotherapy-induced anemia, specifically that caused by cisplatin, as taught by SHINSHI, using the method of CHEUNG, where the motivation would

have been to relive a side-effect of the chemotherapy, as taught by both CHEUNG and SHINSHI. It would further have been obvious to have timed the dosage in the method of CHEUNG at once every two weeks, as taught by SHINSHI, where the motivation would have been to increase the time between doses to improve the convenience of administration, as taught by CHEUNG (p. 421-422).

Claims 225 and 231-233 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423), as applied to claims 204-213, 216-218, 220, 222-224, 226-228, 230, 234, and 237 above, in view of SALMONSON et al. (IDS ref: Scan. J. Urol. Nephrol. (1990) vol. 0, suppl. 129, pp. 1-66).

CHEUNG teaches a method of administering/providing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days, for treatment of anemia, as set forth above. CHEUNG does not teach anemia related to renal failure, blood donation or arthritis.

SALMONSON teaches a method of determining a dosage of EPO using PK/PD information wherein conditions to be treated with his dosing regiment include rheumatoid arthritis, various renal failure associated diseases, and anemia due to blood donation or transfusion (pp. 22-23).

It would have been obvious to one of ordinary skill in the art at the time of invention to have chosen a dosing regimen for any of the disorders of SALMONSON using the method of CHEUNG where the motivation would have been to maintain an enhanced "steady-state" of red blood cells in order to overcome the anemia, as taught by SALMONSON (p. 31).

Claims 219, 220, 235-236, and 242-243 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423), as applied to claims 204-213, 216-218, 220, 222-224, 226-228, 230, 234, and 237 above, in view of FIBI et al. (EP 902085, 3/17/1999)

CHEUNG teaches a method of choosing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days, using recombinant epoietin alfa, as set forth above. CHEUNG does not teach an EPO analog or isoform, or an EPO with a modified glycosylation pattern, specifically one which is hyperglycosylated.

FIBI teaches an EPO analog with altered glycosylation pattern (abstract). FIBI's hyperglycosylated EPO is darbepoetin alpha.

It would have been obvious to one of ordinary skill in the art at the time of invention to have administered the hyperglycosylated EPO of FIBI in the method of CHEUNG where the motivation would have been to use an EPO with improved half-life and biological activity, as taught by FIBI (p. 3, lines 19-22).

Claim 244 is rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423), as applied to claims 204-213, 216-218, 220, 222-224, 226-228, 230, 234, and 237 above, in view of VANCE et al. (US 5,541,158)

CHEUNG teaches a method of choosing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days, using recombinant epoietin alfa, as set forth above. CHEUNG does not teach administering once every four weeks.

VANCE teaches a method of increasing hematocrit and the rate of erythropoiesis by administering EPO one to several times over the course of 4-35 days (col. 12, lines 35-44 and 55-60), which encompasses administration once every four weeks.

It would have been obvious to one of ordinary skill in the art at the time of invention to have administered the EPO in the method of CHAUNG at any of the time intervals taught by VANCE where the motivation would have been to use any timer interval which results in the desired hematocrit level, as taught by VANCE.

Claims 238-241 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423), as applied to claims 204-213, 216-218, 220, 222-224, 226-228, 230, 234, and 237 above, in view of BYERLY et al. (US 6,067,524, filed 1/7/1999).

CHEUNG teaches a method of administering/providing EPO and an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days, for treatment of anemia, as set forth above. CHEUNG does not teach selling EPO nor providing the dosing regimen through a computer system, as in instant claims 238-241.

BYERLY teaches providing dosage information via a computer network (col. 6, lines 26-39) and teaches that this information is an improvement to "point of sale" systems for a drug provided by a pharmacist (col. 6, lines 49-56), thus teaching that drugs maybe sold in conjunction with provision of dosing regimens.

It would have been obvious to one of ordinary skill in the art at the time of invention to have sold the EPO of CHEUNG, in conjunction with providing a dosage regimen, and to have provided the dosage information via a computer, as taught by BYERLY, where the motivation

would have been to improve distribution of the EPO dosing regimens of CHEUNG, as indicated by the teaching of BYERLY that his computerized system for providing/selling drugs and associated information is an improvement.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
7/21/05